

**REMARKS**Rejection of claims 4, 8-9, and 24-30 under 35 USC §101 and §112, 1st paragraph

The Examiner has rejected claims 4, 8-9, and 24-30 under 35 U.S.C. §101 and §112, 1st paragraph, as not being supported by either a specific and substantial asserted utility or a well-established utility and, consequently, one skilled in the art would not know how to use the claimed invention.

In making these rejections, the Examiner states that, although Applicants assert that the protein of SEQ ID NO:2 is a serine/threonine kinase, this is a generic asserted utility, and serine/threonine kinases are a large family of protein kinases with different biological functions and substrate specificity, and the Examiner asserts that the specification does not specifically disclose the specific biological function or substrate specificity of the protein consisting of SEQ ID NO:2. The Examiner further states that the specification does not show any enzyme assays that demonstrate that the protein consisting of SEQ ID NO:2 has enzymatic activity. Thus, the Examiner concludes that there is no disclosed or "real world" utility associated with the nucleic acid of SEQ ID NO:1 or the protein of SEQ ID NO:2 and that further research is required to determine the main utility of the nucleic acids and protein; consequently, the claimed invention has no specific and substantial asserted utility or a well-established utility.

Applicants respectfully assert that, contrary to the Examiner's assertions, the claimed invention is supported by both specific and substantial asserted utilities as well as utilities that are well established in the art.

Applicants agree with the Examiner that the serine/threonine kinases are a large family of protein kinases. Accordingly, Applicants have more specifically characterized the protein of SEQ ID NO:2 as being homologous to SNF kinases, which are a specific group of serine/threonine kinases having specific functions. For example, as described in the 4<sup>th</sup> full paragraph on page 5 of the specification, SNF kinases specifically function to derepress glucose-repressible genes. SNF kinases are also involved in signal transduction and development. For example, Hunk-1 kinase, an SNF kinase, is expected to be involved

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in tissue development and cancer formation. Myocardial SNF1-like kinase (msk) regulates HEK kinase, an ephrin receptor type kinase.

The Examiner further stated that the specification does not show any enzyme assays that demonstrate that the protein of SEQ ID NO:2 has enzymatic activity. However, assays are not needed to satisfy the requirements of 35 U.S.C. §101 and §112, 1st paragraph. Instead, Applicants have conducted extensive bioinformatic analysis, the methods of which are well-established in the art as being a suitable alternative to "wet lab" work such as enzymatic assays for accurately predicting protein activity. The results of the analysis, which are provided in the Figures, clearly show that one of ordinary skill in the art would expect the protein of SEQ ID NO:2 to function as a serine/threonine kinase enzyme, even in the absence of enzymatic assays to validate this activity. For example, in addition to the top 10 BLAST hits shown on page 2 of Figure 1 (which consistently indicate that SEQ ID NO:2 shares the highest degree of sequence similarity with serine/threonine kinases), Prosite analysis shown on page 2 of Figure 2 identifies a serine/threonine protein kinase active-site signature at residues 154-166 of SEQ ID NO:2, and Hmmer/Pfam analysis shown on page 4 of Figure 2 further verifies the presence of a eukaryotic protein kinase domain.

Thus, it is clear that the claimed invention is supported by specific and substantial asserted utilities as well as well-established utilities, and, consequently, one skilled in the art would know how to use the claimed invention. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 4, 8-9, and 24-30 under 35 U.S.C. §101 and §112, 1st paragraph.

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### Conclusions

Claims 4, 8-9, and 24-30 remain pending.

In view of the above remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,

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